PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM (CATEGORY-1)

Protocol Title: An Event-Driven, Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy, Safety, Immunogenicity, and Lot-to-Lot consistency of BBV152, a Whole-virion Inactivated SARS-CoV-2 Vaccine in Adults ≥18 to Years of Age.

.Protocol Number	:	BBIL/BBV152-C/2020
Version & Date	:	Version: 3.0; Dated 20 Oct2020
Sponsor	:	Bharat Biotech International Limited, Hyderabad, Telangana – 500078
Study Investigator	:	
Study Site and address	:	
Phone number(s)	:	
Screening Number	:	

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making the decision.

A person who takes part in a research study is called a research or study subject. In this consent form "you" always refers to the research (study) subject.

SUMMARY

You are being asked to participate in a research study. The purpose of this consent form is to help you decide your participation in this study. To be in this study you must provide informed consent. Please read this form carefully. "Informed consent" includes:

- Reading this document or having it read to you,
- Having the study doctor or study staff explain the study to you,
- Asking questions about anything that is not clear, and
- You may take home an unsigned copy of this document if you require time to think about it and to talk to family or friends before you make the decision.

You should not agree to participate in this study until all of your questions are answered satisfactorily.

After reading and discussing the information in this consent form you should know:

- Why this study is being done
- What will happen during the research
- What vaccine or procedures will be used
- Any possible benefits to your participation
- The possible risks to your participation

If you take part in this study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY

BBV152 is an investigational COVID-19 vaccine. This study is to know whether the vaccine (BBV152-B) is producing desired effect (efficacy), safety, and immune response (immunogenicity). The study will recruit individuals until the total number of 130 required subjects are accrued, with a virologically (RT-PCR test positive) confirmed symptomatic cases (i.e. persons who are positive for RT-PCR and are having symptoms of coronavirus disease (COVID-19). After reaching the target number of 130 COVID-19 cases, study will continue to assess only the safety until the study completion.

The study will also assess whether different batches of the vaccine are consistently producing the desired immune response (The Lot to Lot consistency study). This Lot-to-lot consistency study will be included as a part of the Phase 3 (Efficacy) study. The study to check immune response (Immunogenicity study) of the 2-dose regimen of BBV152 vaccine will be conducted in a subset of 600 (450 vaccine: 150 control) participants, across three consecutive manufacturing vaccine batches (Lots).

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate in the study or you may leave the study at any time. Your decision will not cause any penalty or loss of benefits to which you are entitled.

The study doctor or the sponsor may stop your participation in this study at any time without your consent for any of the following reasons:

- It is in your best interest;
- You do not later consent to any future changes that may be made in the study plan; or
- For any other reason.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some of the concluding procedures of the study so that we can record your general health condition and reasons for withdrawal.

STUDY PARTICIPATION AND PROCEDURES

A total of 25,800 subjects will be enrolled and randomly assigned equally to receive either BBV152-B vaccine OR Placebo (i.e inert substance having no effect). You will be classified into three categories based on the sites where you have been enrolled. The study procedure will be different for each category.

CATEGORY I (Symptomatic cases):

Visit 1 Baseline (Month 0):

You will be checked whether you are eligible for the study based on the medical history and physical examination. If you are eligible (in good general health or stable pre-existing disease as per the discretion of the Principal investigator (doctor who is the main person responsible for

conducting the study), blood sample (5 mL) and swab will be collected through nose (Nasopharyngeal swab) prior to vaccination. A study vaccine/placebo will be administered. Following vaccination, you will remain at the study site for at least 30 min of observation to record any immediate side effects.

Visit 2 (Month 1+2 days):

You will return to the OPD for vitals (Temperature, Pulse rate, BP, Respiratory rate, SpO2) physical examination (general and systemic examination), and specific symptoms for coronavirus disease (COVID-19). A study vaccine/placebo will be administered. Following vaccination, you will remain at the study site for at least 30 min of observation to record any side effects.

You will be telephonically followed-up from 3rd month to 12 month for safety.

RANDOMIZATION

You will be randomly assigned (randomization) to receive two doses of either BBV152 vaccine or placebo so that you will have equal chance of receiving either vaccine or placebo. Since three vaccine batches (lots) of BBV152 vaccine will be used in the trial, randomization assignments will in 1:1 ratio, corresponding to 3 participants receiving vaccine from each of the 3 lots of BBV152 and 3 placebo recipients, via an interactive web response system (a web based system for assigning the participants to randomly receive either the vaccine or placebo). If you have any underlying disease (based on your medical history and physican examination before the administration of vaccine or placebo, you will be randomly assigned to receive either vaccine or placebo based on your disease condition.

DURATION OF THE STUDY

Your participation in the study will be approximately 12 months.

YOUR RESPONSIBILITIES IN THE STUDY

1. You should not participate in any other clinical trial during the study period.
2. Available for clinical follow-up throughout the study period via telephone contact as well as clinic visits.
3. Agree to keep a daily record of symptoms for the duration of the study

Precautions need to be taken for Protect yourself and others from the spread COVID-19:

- Regularly and thoroughly clean your hands with an alcohol-based hand rub or wash them with soap and water.
- Maintain at least 2 meter (6 feet) distance between yourself and others.
- Avoid going to crowded places.

- Avoid touching eyes nose and mouth.
- Make sure you, and the people around you, follow good respiratory hygiene. This means covering your mouth and nose with your bent elbow or tissue when you cough or sneeze. Then dispose of the used tissue immediately and wash your hands.
- Stay home and self-isolate even with minor symptoms such as cough, headache, mild fever, until you recover. Have someone bring you supplies. If you need to leave your house, wear a mask to avoid infecting others.
- If you have a fever, cough and difficulty breathing, seek medical attention, but call by telephone in advance if possible and follow the directions of your local health authority.
- Keep up to date on the latest information from trusted sources, such as WHO or your local and national health authorities.

WHAT ARE THE RISKS OR DISCOMFORTS OF TAKING PART?

POTENTIAL BENEFITS OF STUDY PARTICIPATION

The target study population for this study is adults with no known history of SARS-CoV-2 infection but whose locations or circumstances put them at high risk of COVID-19. The following benefits may accrue to participants.

- The BBV152 vaccine may be an effective vaccine against COVID-19.
- Contributing to the development of a vaccine against COVID-19, a current pandemic disease.

RISKS FROM STUDY PARTICIPATION

Vaccination with corona virus vaccine, BBV152 is the first ever vaccine used in clinical trials. Based on experiences with other similar vaccines you may experience the following symptoms after vaccination:

- Anaphylaxis
- Pain at injection site
- Redness at injection site
- Swelling at injection site
- Hardness at injection site
- Systemic symptoms like raised temperature or fever, chills, headache, , nausea, , vomiting, weakness, muscle pains and joint pains.

You may experience some pain and/or swelling of your arm from having blood drawn the number of times specified in the study procedures above. Drawing of blood can cause local bruising and reactions at the site of injection such as redness, swelling, and heat sensation.

WHAT WILL HAPPEN IF SOME NEW INFORMATION ABOUT THE VACCINE IS IDENTIFIED

Sometimes during the course of a research project, if new information becomes available about the vaccine, then you will be informed in a timely manner, as it may be relevant. During the study, we may find new medical information about the subject. We will share this with you right away if it is important to your health. We may advise you to do other tests to check this new information.

WHAT ARE BENEFITS & COSTS/PAYMENT FOR PARTICIPATION?

Benefits

By participating in this study, you will learn about Coronavirus (COVID-19) disease and how to prevent it. Your participation in this study will help in generating information about the effect of this novel vaccine and lead the direction for further development of the vaccine so that it can

become available to general public. If successful, the vaccine will be able to prevent Coronavirus infection or the symptoms caused by it and will benefit a larger population.

Costs/payment

You will not have to bear any cost for participating in this study nor will you receive any monetary benefit from participating in the study. However, you will be reimbursed towards cost incurred for travel or loss of daily wages by you of Rs. 750 for your participation in the study. Even if you do not complete the study for any reason, you will be reimbursed for each visit which you have completed.

WHAT ARE THE ALTERNATIVE TREATMENTS?

Currently, there are no vaccines commercially available to prevent SARS-COV-2 virus infection or COVID-19 disease.

MAY I WITHDRAW OR REVOKE (CANCEL) CONSENT?

You may withdraw or take away consent to use and disclose your health information at any time without giving any reason. If you withdraw consent, your will not be able to stay in this study further.

When you withdraw consent, no new health information will be gathered after that date. Information that has already been gathered and the samples collected may still be used in the research and given to others.

CONFIDENTIALITY

All the details related to you will be kept confidential. We will use a number instead of your name or other items that could identify you and your family personally on the record. The study doctor, sponsor/agents for the sponsor, regulatory authorities, and the ethics committee at the site may get this information.

Study information collected about you will be given to the sponsor. "Sponsor" means any persons or companies that are working for or with the sponsor, or owned by the sponsor.

It will also be given to the regulatory authorities of India. It may be given to governmental agencies in other countries where the vaccine may be considered for approval. Medical records which identify you and the consent form signed by you may be looked at for research or regulatory purposes.

You should also keep the data confidential and do not disclose any information that may reveal your confidentiality.

Why will this information be used and/or given to others?

- To conduct the research,
- To interpret and analyze the results, and
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

COMPENSATION FOR INJURY

If you decide to participate in the study, you will have to undergo all the study procedures explained above and provide the study related information to the study doctor and strictly follow the instructions of study doctors. In the event of any injury that are related to the clinical trial you will be provided free medical care as advised by the study doctor as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

In the event of an injury or death that is related to the clinical trial, M/s. Bharat Biotech International Limited, Hyderabad shall provide financial compensation as per applicable guidelines of the national regulatory authority.

During the course of the clinical trial, in case if you receive a placebo and any death occurs the sponsor shall not be responsible for any compensation.

You (your nominee or legal heir, as applicable) have the right to contact the Sponsor (Bharat Biotech International Ltd. or its representative) for the purpose of making claims in the case of study related injury or death. Contact information for the Sponsor (or its representative) is available with your study doctor.

As a liability / responsibility of the Sponsor, you will be covered by an insurance policy.

SOURCE OF FUNDING FOR THE STUDY

Bharat Biotech International Limited will fund for the study

WHO SHOULD I CALL IF I HAVE ANY QUESTIONS?

If you have any questions about the study or your participation in it or if you feel that you have had a research related injury or have a bad reaction to the study vaccine, you should contact Dr. _____ principal investigator of this study at telephone number ___ or another study staff.

If you have any questions about the rights you have while taking part in this study, call the Secretary of IEC, Mr/Mrs. _____ ___ at telephone numbe _____

Sign the participant informed consent form only if your questions have been answered to your satisfaction.

PARTICIPANT INFORMED CONSENT FORM

Study Title: An Event-Driven, Phase 3, Randomized, Double-blind, Placebo-controlled Multicenter Study to Evaluate the Efficacy, Safety, Immunogenicity, and Lot-to-Lot consistency of BBV152, a Whole-virion Inactivated SARS-CoV-2 Vaccine in Adults ≥18 Years of Age.

Protocol Number: BBIL/BBV152-C/2020 **Version Number & Dated:** 3.0, 20 Oct 2020

Subject Initials: _____ **Subject Name :**

Screening Number: _____ **Date of Birth and Age:**

Educational Qualification: _____

Occupation: (Please tick as appropriate)

Address of the subject: _____

Contact Number: _____

Annual Income of the subject: _____

Site Name: _____

Name and Address of the Nominee to the subject (In case of death):

_____

Relationship to subject: _____

		Initial the box (Subject)
(I)	I confirm that I have read/have had it read and understood the information sheet dated 20 Oct 2020 for the above study and have had the opportunity to ask questions.	[ ]
(II)	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[ ]
(III)	I understand that the sponsor of the clinical trial, others working on the sponsor's behalf, the ethics committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw my consent from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	[ ]
(IV)	I agree not to restrict the use of any data or results that arise from this study provided such use is only for scientific purpose(s)	[ ]
(VI)	I agree to allow storage and future use of my blood sample for research.	[ ]
(VII)	I agree to take part in the above study.	[ ]

Subject's Name: _____

Signature or thumb Impression: _____

Date & Time: _____

Principal Investigator/Designee taking Consent:

Name: _____

Signature _____

Date &Time _____

Name of the Impartial Witness _____

(*In case subject is illiterate*)

Signature: _____

Date & Time__ _____

Contact Details of Impartial Witness_____

(A copy of the participant Information Sheet and duly filled Informed Consent Form shall be handed over to subject or his/her attendant)

AUDIO-VISUAL RECORDING CONSENT FORM

BBIL/BBV152-C/2020: An Event-Driven, Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy, Safety, Immunogenicity, and Lot-to-Lot consistency of BBV152, a Whole-virion Inactivated SARS-CoV-2 Vaccine in Adults ≥18 Years of Age.

Protocol Number: BBIL/BBV152-C/2020 **Version Number & Dated:** 3.0, 20 Oct 2020

Subject Initials: _ _

Screening Number: _ _____ **Date of Birth**

Age_ **SiteName**_____

I do not have any objection for the audio video recording of the informed consent process which will be conducted by the Investigator/designee.

I have been informed that the recording of informed consent process will be undertaken by site staff in a confidential manner protecting my identity. The recorded clipping will not be used for any purpose other than review/verification of informed consent process by regulatory authorities/ Institutional Ethics Committee. I have been informed that the recorded clipping will be coded so that no personally identifiable information is visible on them, the recordings will be archived securely at site with other study documents.

I hereby voluntarily confirm my willingness for audio video recording of informed consent process for the above mentioned clinical trial.

_____

Name of participant's Parent/ LAR and relationship to participant

_____ _____

Parent's/LAR's Signature/Thumb Impression Date & Time

_____ _____

Signature of person delegated to conduct informed consent discussion Date & Time

_____ _____

Investigator Signature Date & Time